

REMARKS

The Office action mailed 14 August 2008, has been received and its contents carefully noted. Claims 29-36 and 39 were pending, claims 31-34 and 36 were withdrawn from consideration, and claims 29, 30, 35 and 39 were rejected. Reconsideration in view of the following is respectfully requested.

Rejection under 35 U.S.C. 102(b)

The Examiner rejected claims 29 and 35 under 35 U.S.C. 102(b) as being anticipated by Doretti et al. Specifically, it appears that the Examiner deems that determining the activity or the concentration of the protein using a sensitivity coefficient for each substrate and for each protein is merely an intended use rather than a means-plus-function limitation.

Applicants respectfully submit that Doretti et al. does not teach each and every limitation of the claimed invention. Specifically, the devices as claimed in claims 29 and 35 require a means for determining the activity or the concentration of the protein using a sensitivity coefficient for each substrate and for each protein. The instant specification discloses software as corresponding structure and related mathematical algorithms. See e.g. page 28 line 16 to page 29 line 13 and the Examples.

Doretti et al. does not teach or suggest any structure or means which determines the activity or concentration of a protein using a sensitivity coefficient as required and defined in the instant claims. The Examiner points to a spectrophotometer output or strip chart or data collection means as reading on “means for determining activity”. The “means for determining activity” according to Doretti et al., however, is completely different from “means for determining activity based on a sensitivity coefficient” according to the present invention.

Applicants respectfully submit that the patentable significance of the sensitivity coefficient of the present invention has been overlooked. Throughout the prosecution of this application thus far, the Examiner does not appear to appreciate the scope and meaning of the sensitivity coefficient of the instant invention or its patentable significance. Specifically, the Examiner has incorrectly equated the linear relationships disclosed in Doretti et al. as being the same as the sensitivity coefficients of the instant invention. See e.g. Office Actions mailed 03/29/07 and 08/31/07. Thus, Applicants surmise that the Examiner still does not appreciate the

claim limitations relating to the sensitivity coefficients which patentably distinguish the instant invention from that of the prior art.

The Examiner's lack of appreciation of the sensitivity coefficient limitations and the distinction between a protein and a substrate in the instant claims is evidenced by the Examiner asserting that the "functional intended use with diluting, calculating and extracting sensitivity coefficients ... is given no patentable weight". Applicants respectfully submit that the Examiner mischaracterizes lines 10-21 of claim 29 as intended use limitations. Applicants respectfully urge that lines 10-21 of claim 29 are provided to clearly define the meaning of a sensitivity coefficient according to the instant invention.

To ignore the meaning of a sensitivity coefficient is to ignore the patentable significance of the means for determining the activity or the concentration of the protein using a sensitivity coefficient (as defined in the instant claims). If one correctly understands the meaning of a sensitivity coefficient according to the present invention, one will appreciate that means of Doretti et al. are completely different from the claimed means for determining the activity or the concentration of the protein of the present invention.

The Examiner has also confused a protein (enzyme) with its substrate and vice versa. See e.g. Office Action mailed 01/29/08. In the last Office Action mailed 14 August 2008, the Examiner did not rebut Applicants' argument that the Examiner mischaracterizes the disclosure of Doretti et al. In particular, the Examiner failed to support her assertion that Doretti et al. teaches a device which measures the concentration or activity of a protein in a sample using the sensitivity coefficient as claimed after Applicants provided ample evidence and reasoning as to why a substrate is not a protein and as such, the biosensor of Doretti et al. is incapable of measuring a protein in a sample since employs a given amount of a protein immobilized on a membrane to detect and measure a substrate for the protein. Instead, in the last Office Action, the Examiner again mischaracterizes Doretti et al. by stating that Doretti et al. teaches a biosensor for the determination of cholinesterase* on a membrane and avoids Applicants' plea for the Examiner to acknowledge that a substrate is not a protein.

* As previously pointed out, Doretti et al. discloses detecting and measuring a substrate (which is not a protein) by using a given amount of a protein (cholinesterase) that is immobilized on a membrane.

To ignore the distinction between a protein and its substrate is to ignore the patentable distinction between means for measuring a protein with means for measuring a substrate. If one correctly understands the difference between a protein and a substrate, one will appreciate that the means of Doretti et al. are not the same as and can not be used as the means for determining the activity or the concentration of a protein of the present invention.

Since Doretti et al. does not teach or suggest a sensitivity coefficient according to the claimed invention and Doretti et al. does not teach or suggest any means for determining the activity or concentration of the protein based on a sensitivity coefficient as required by the instant claims, the claimed invention is novel and unobvious.

Therefore, the rejection under 35 U.S.C. 102(b) should properly be withdrawn.

Rejection under 35 U.S.C. 103(a)

The Examiner rejected claims 29, 30, 35, and 39 under 35 U.S.C. 103(a) as being unpatentable over Doretti et al. in view of Magnotti et al. and further in view of Ellman et al. Specifically, the Examiner deemed that it would have been obvious “to develop a handheld device with a biosensor (as taught by Doretti et al.) and a cartridge ... to monitor enzyme activity because Doretti et al. teach a biosensor to detect enzyme activity ...” (emphasis added).

Applicants respectfully submit that the cited art, alone or in combination, do not teach or suggest the claimed invention. Specifically, as explained above, the biosensor of Doretti et al. is incapable of detecting an enzyme/protein. Instead, the device of Doretti et al. discloses detecting cholines which are not proteins. Magnotti et al. and Ellman et al. do not alleviate this deficiency of Doretti et al.

Applicants also respectfully urge that submit that the cited art, alone or in combination, do not teach or suggest the means for determining the activity or the concentration of the protein in accordance with the present invention. As provided above, Doretti et al. does not teach or suggest a means which employ a sensitivity coefficient according to the instant invention for determining the activity of concentration of a protein. Magnotti et al. and Ellman et al. do not alleviate this deficiency of Doretti et al.

Thus, Applicants respectfully submit that the combination of Doretti et al., Magnotti et al., and Ellman et al. does not result in the claimed invention.

Therefore, a prima facie case of obviousness has not been established and the rejection under 35 U.S.C. 103(a) must properly be withdrawn.

Request for Rejoinder

Applicants respectfully request rejoinder of the withdrawn claims which ultimately depend on claim 29.

Request for Interview

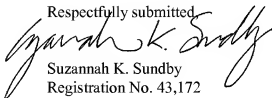
Either a telephonic or an in-person interview is respectfully requested should there be any remaining issues.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Therefore, it is respectfully requested that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. 1.136(a), and any fees required therefor are hereby authorized to be charged to **Deposit Account No. 210-380**, Attorney Docket No. **034047.003DIV1 (WRAIR 00-23)**.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Suzannah K. Sundby', is written over the typed name and registration number.

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